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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,824	11/19/2003	Paul O. Sheppard	97-11D1	8035

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EXAMINER	
REDDIG, PETER J	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 04/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/716,824	SHEPPARD ET AL.	
	Examiner	Art Unit	
	Peter J. Reddig	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-12 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 2, drawn to an expression vector comprising the operably linked transcription promoter and a DNA segment which encodes ONE Zsig9 polypeptide which contains an epitope bearing region of a Zsig9 polypeptide, classified in class 435, subclass 320.1.

(Upon election of Group I, applicant must further choose ONE polypeptide SEQ ID NO. from Claim 2: as each polypeptide represents an independent invention, not a species.)

II. Claims 3 and 4, drawn to ONE isolated Zsig9 polypeptide, classified in class 530, subclass 300; class 530, subclass 350.

(Upon election of Group I, applicant must further choose ONE polypeptide SEQ ID NO. from Claim 3 or 4: as each polypeptide represents an independent invention, not a species.)

III. Claims 5-11, drawn to an antibody that specifically binds ONE Zsig9 polypeptide and a method to produce said antibody, classified in class 530, subclass 387.1.

(Upon election of Group I, applicant must further choose ONE polypeptide SEQ ID NO. from Claim 5: as each polypeptide represents an independent invention, not a species.)

IV. Claims 12, drawn to an anti-idiotypic antibody that specifically binds an antibody to ONE Zsig9 polypeptide, classified in class 530, subclass 387.2.

(Upon election of Group I, applicant must further choose ONE polypeptide SEQ ID NO. from Claim 12: as each polypeptide represents an independent invention, not a species.)

The inventions are distinct, each from the other because of the following reasons:

The inventions are distinct, each from the other because of the following reasons:

The DNA of Group I is related to the polypeptide of Group II by virtue of the fact that a DNA segment contained within the vector DNA codes for the protein. The DNA molecule has utility for the recombinant production of the protein in a host cell. Although the DNA and the protein are related, since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by other and materially distinct processes, such as purification from the natural source. Further, DNA can be used for processes other than the production of protein, such as nucleic acid hybridization assays.

Furthermore, searching the inventions of Groups I and II together would impose a serious search burden. In the instant case, the search of the polypeptides and polynucleotides are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate database. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequences of interest there may be journal articles devoted solely to polypeptides, which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers, which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. In addition, the claims include 9 distinct sequences inclusive of various complements and fragments. This search requires an extensive analysis of the art retrieved in a

sequence search and will require an in-depth analysis of technical literature. As such, it would be burdensome to search the inventions of Groups I and II.

The polynucleotide of Group I and the antibody of Groups III and IV are patentably distinct for the following reasons:

The antibodies of Groups III and IV includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarily determining regions (CDRs). Polypeptides, such as the antibodies of Groups III and IV, which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of Group I will not encode antibodies of Groups III and IV, and the antibodies of Groups III and IV cannot be encoded by a polynucleotide of Group I. Therefore, the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of Groups I, III, and IV would impose a serious search burden since a search of the polynucleotides of Group I would not be used to determine the patentability of any antibody of Groups III and IV, and vice-versa.

The polypeptide of Group II and the antibody of Group III and IV are patentably distinct for the following reasons:

While the inventions of Groups II-IV are polypeptides, in this instance the polypeptides of Group II represent various Zsig9 polypeptides, whereas the polypeptides of Group III and IV encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarily determining regions (CDR) that function to bind an epitope. Thus the polypeptides of Group II and the antibodies of Group III are structurally distinct molecules; any relationship between a polypeptide of Group II and an antibody of Group III is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

In this case, the polypeptides of Group II encompass large molecules which contain potentially hundreds of regions to which an antibody may bind, whereas the antibodies of Groups III and IV are defined in terms of its binding specificity to a small structure within the claimed polypeptides. Furthermore, searching the inventions of Group II-IV would impose a serious search burden. The inventions have separate status in the art as shown by their different classifications. A polypeptide and an antibody that binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of Groups III and IV. Furthermore, antibodies that bind to an epitope of a polypeptide of Group II may be known even if a polypeptide of Group II is novel. In addition, the technical literature search for the polypeptides of Group II and the antibodies of

Groups III and IV are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

The antibodies of Group III and Group IV are patentably distinct for the following reasons:

While both groups claim antibodies the antibodies are distinct because they are directed to different epitopes (Zsig9 epitopes for Group III and the Zsig9 antibody for Group IV). Additionally, the inventions are distinct because the biological process involved in antibody generation is variable and unpredictable in nature. It is the structural differences generated by these processes that allow the antibodies to recognize different epitopes. It is unlikely that any two antibodies, even those directed to the same epitope, have the same structure. Thus, the inventions of the Groups III and IV are distinct. Since the products are distinct and have been classified separately, indicating a separate status in the art, searching all of the claims of both groups would invoke a burdensome search.

Because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Applicant is advised that the reply to this restriction requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571)272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Peter J. Reddig, Ph.D.
Examiner
Art Unit 1642

PJR

GARY B. NICKOL, PH.D.
PRIMARY EXAMINER